Supreme Court, U.S.
FILED

No. 603 AUG 20 1996

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In The

Supreme Court of the United States

October Term, 1996

Catherine W. Griffin,
Petitioner,

v.

Medtronic, Inc.,
Respondent,

On Petition for a Writ of Certiorari to
The United States Court of Appeals
For the Fourth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments to the Food, Drug & Cosmetic Act preempt state law products liability claims, an issue on which the Fourth Circuit decision in this case directly conflicts with a relevant decision of the Supreme Court?

Catherine W. Griffin respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

OPINIONS BELOW

The opinion of the Court of Appeals for the Fourth Circuit, App. at 1-9, is reported at 82 F.3d 79 (4th Cir. 1996). The opinion of the District Court for the District Court of Maryland, App. at 10-13, is reported at 840 F.Supp. 396 (D. Md. 1995).

JURISDICTION

The Petition for Rehearing was denied by the Court of Appeals on May 29, 1996. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

U.S. Const., Article VI ..... App. 14

21 U.S.C. § 360k ..... App. 14-15

21 U.S.C. § 360h(d) ..... App. 15

21 C.F.R. § 808.1(d) ..... App. 15-16

STATEMENT OF THE CASE

Mrs. Griffin brought state products liability claims against Medtronic, Inc. seeking damages for the injuries caused by Medtronic cardiac

pacemakers. The district court granted summary judgment in favor of Medtronic, Inc., concluding that the Medical Device Amendments to the Food Drug and Cosmetic Act preempted all claims for damages under state law. The Court of Appeals for the Fourth Circuit largely affirmed, holding that the Amendments preempted all of Mrs. Griffin's product liability claims except for breach of express warranty.

A. Statement of Facts

Mrs. Griffin suffers from cardiac malfunction which required her to have a pacemaker implanted to artificially regulate, control and pace her heart. A cardiac pacemaker consists of a pulse generator and a lead or an electrode. In February of 1984, Mrs. Griffin had a Medtronic Spectrax model 8422 dual chamber generator and model 6972 polyurethane lead implanted. In March of 1986, this pacemaker failed and a Medtronic Spectrax model 8420 dual chamber generator and a Medtronic model 4012 polyurethane lead were implanted in her chest. In December of 1989, this pacemaker also failed and was explanted from Mrs. Griffin's chest. The failed leads remain implanted in Mrs. Griffin's chest. Both of the failed pacemakers were manufactured and sold by Medtronic.

The failed pacemakers are subject to the Medical Device Amendments of 1976 ("Amendments"). Under the Amendments, the FDA classifies all medical devices into three groups. 21 U.S.C. §360c(a). The FDA placed the pacemaker generators and leads implanted in Mrs. Griffin into Class III in 1980. 21 C.F.R. §870.3610. Both models were classified as substantially equivalent to devices in commercial distribution prior to May 28, 1976, the effective date of the Amendments. Medtronic therefore submitted a section 510(k) "premarket notification" on the grounds that its devices were "substantially equivalent to such devices". The 510(k) notification constitutes an exemption from the class III "premarket approval" regulatory process that would otherwise have applied to the devices. 21 U.S.C. §360c(f)(1).

B. Procedural History

This is a diversity action, originally brought by Catherine Griffin on December 4, 1992, a citizen of Maryland, in the Circuit Court for

Baltimore City, Maryland, which was removed to the United States District Court for the District of Maryland pursuant to 28 U.S.C. §1332. The district court granted summary judgment, holding that the Amendments preempted each of Mrs. Griffin's claims. App. at 10-13. The court of appeals affirmed except with respect to the claim for breach of express warranty based on warranties made apart from the labeling, packaging or promotion of the product. App. at 1-9.

REASONS FOR GRANTING THE PETITION

The preemptive scope the Amendments was defined by the Supreme Court on June 26, 1996. *Medtronic, Inc. v. Lohr,* 56 F.3d 1335 (11th Cir. 1995), Nos. 95-754 and 95-886 (June 26, 1996). The Fourth Circuit's decision this case directly conflicts with the Supreme Court's decision in *Lohr*.

I. The Fourth Circuit's Decision Irreconcilably Conflicts with Supreme Court Decisions

Griffin is in direct conflict with this Court's recent ruling in *Lohr* which creates an obvious, irreconcilable conflict: the Supreme Court held that the Amendments do not preempt products liability law, but here the Fourth Circuit found that almost all of Mrs. Griffin's claims are preempted. The courts differ both in their reading of the statute and, more fundamentally, in their approach to the doctrine of preemption.

On June 26, 1996, the Supreme Court announced its decision in *Medtronic, Inc. v. Lohr,* 56 F.3d 1335 (11th Cir. 1995), Nos. 95-754 and 95-886 (June 26, 1996). The Supreme Court held that the Medical Device Amendments do not preempt state tort claims, including negligent design claims and strict liability claims based upon defective design, manufacturing defect or failure to warn. *Id.*
This decision directly overrules the Fourth Circuit's opinion in *Griffin*.

The court in *Griffin* stated "[T]he preemption issues presented by this appeal are controlled by our recent decision in *Duvall*..." *Griffin v. Medtronic, Inc.*, 82 F.3d 79, 81 (4th Cir. 1996). On July 1, 1996, the Supreme Court granted certiorari and vacated the Fourth Circuit's

decision in *Duvall v. Bristol-Myers-Squibb, Co.*, 65 F.3d 392 (4th Cir. 1995), *vacated*, No. 95-1010 (July 1, 1996), and remanded the case for further proceedings. Like *Griffin*, *Duvall* involves preemption of state tort claims regarding a Class III medical device that was approved for marketing pursuant to a 510K "substantially equivalent" notification, not pursuant to a premarket approval process.

The Fourth Circuit decision in *Griffin*, which involves an important federal question, directly conflicts with the Supreme Court's decision in *Lohr*. Therefore, certiorari should be granted in this case. Furthermore, since the Fourth Circuit held that the preemption issues in *Griffin* were "controlled by our recent decision in *Duvall*", and last month the Supreme Court granted certiorari and vacated the Fourth Circuit's decision in *Duvall*, justice demands that certiorari be granted in this case.

CONCLUSION

For the above reasons, Mrs. Griffin respectfully requests that this Court grant her petition for a writ of certiorari.

Respectfully submitted,

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PUBLISHED
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CATHERINE W. GRIFFIN,	*	
	*	
Plaintiff-Appellant,	*	
v.	*	No. 94-1219
	*	
MEDTRONIC, INCORPORATED,	*	
	*	
Defendant-Appellee.	*	
	*	

* * * * * * * * * * * * * * *

Appeal from the United States District Court
for the District of Maryland, at Baltimore
Frederic N. Smalkin, District Judge.
(CA-93-60-S).

Argued: September 27, 1994.

Decided: April 30, 1996.

Before WIDENER and MOTZ, Circuit Judges, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Affirmed by published opinion. Senior Judge MICHAEL wrote the opinion, in which Judge WIDENER and Judge MOTZ joined.

COUNSEL

ARGUED: Kristen Atkins Brinster, Seidenman, Sutherland & Lynn, P.A., Baltimore, Maryland, for Appellant. Harley Thomas Howell, Benjamin Rader Goertemiller, Howell, Gately, Whitney & Carter, Towson, Maryland, for Appellee. **ON BRIEF:** Jerome J. Seidenman, John R. Sutherland, Seidenman, Sutherland & Lynn, P.A., Baltimore, Maryland, for Appellant. John S. Bainbridge, Jr., Howell, Gately, Whitney & Carter, Towson, Maryland, for Appellee.

OPINION

MICHAEL, Senior District Judge:

Catherine Griffin appeals the decision of the district court granting summary judgment to Medtronic, Inc. ("Medtronic") on the grounds that Griffin's claims are preempted by 21 U.S.C.A. § 360k (West Supp.1995), enacted as part of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act. On the recent authority of *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir.1995), we affirm in part, reverse in part and remand.

I.

In 1984, a pacemaker, manufactured and sold by Medtronic, was implanted in Griffin's chest to help regulate and control her heart rate. The pacemaker consisted of a dual chamber generator and polyurethane leads. In 1986, the pacemaker failed and was removed. However, portions of the leads remained in Griffin's chest. Griffin's physicians inserted a new Medtronic pacemaker which ultimately failed in 1989. Doctors removed most of the second pacemaker, but once again, portions of the leads remained in Griffin's chest. Griffin then received yet another Medtronic pacemaker which has not functioned properly to date, allegedly because of the remnants of the leads left in Griffin's chest.

In 1992, Griffin brought the current suit against Medtronic in

Maryland state court. Her complaint states five counts: (1) negligent design and manufacture; (2) breach of express warranty; (3) breach of an implied warranty of fitness for a particular purpose; (4) strict liability for defective manufacture; and (5) intentional misrepresentation of the defective condition of the pacemakers. Medtronic removed the case to federal court on the basis of diversity of citizenship.

The district court, relying on the authority of *Stamps v. Collagen Corp.*, 983 F.2d 1416 (5th Cir.1993), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.1993), ruled that Griffin's claims were preempted by § 360k of the MDA[1] and, accordingly, granted Medtronic's motion for summary judgment. No material facts are in dispute. The appeal presents questions of law subject to de novo review. *Higgins v. E.I. DuPont de Nemours & Co.*, 863 F.2d 1162, 1166-1167 (4th Cir.1988).

II.

A.

The preemption issues presented by this appeal are controlled by our recent decision in *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir.1995). The plaintiff in *Duvall* brought several state-law claims against the manufacturer of a penile prosthesis after undergoing surgery to implant the prosthesis.[2] In ruling that the majority of plaintiff's claims

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1 Subject to a possible exemption not claimed here, section 360K provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k.

2 Under the framework of the MDA, penile inflatable implants are classified as "Class III" medical devices, and as such, are subject to the most rigorous regulation. *Duvall*, 65 F.3d at 396, 21 C.F.R. § 876.3350 (1995). A manufacturer must generally receive approval from the Food

were preempted by § 360k, we held that "state-law claims are preempted by § 360k to the extent that, if successful, such claims would impose requirements under state law different from or in addition to requirements applicable to a device under the MDA." *Id.* at 398. With this language as a baseline, we concluded that plaintiff's breach of implied warranty, strict liability, and negligence claims were necessarily preempted by § 360k. However, we held with respect to plaintiff's breach of express warranty claim that "although § 360k preempts express warranty claims to the extent that they are based on FDA-mandated labeling, packaging, and advertising, it does not preempt an express warranty claim that is based on a manufacturer's voluntarily-made representations regarding its product." *Id.* at 400-401. We therefore reversed and remanded, for further consideration in light of that holding, the district court's grant of summary judgment for Medtronic on the express warranty claim.

B.

[1] Given the authority of *Duvall*, we deal only briefly with Griffin's arguments.[3] Griffin's breach of implied warranty, strict liability, and negligence claims are preempted by § 360k because were Griffin to prevail on those claims, Medtronic would be burdened with requirements different from or in addition to those applicable to pacemakers under the MDA. As did the plaintiff in *Duvall*, Griffin here argues that these state-law claims, if successful, would not impose any different or additional requirements on Medtronic because the MDA does not impose specific requirements on pacemakers in the first instance.

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and Drug Administration ("FDA") before marketing a Class III device. However, the prosthesis was brought to market via the "substantially equivalent" mechanism outlined at 21 C.F.R. § 807.100(a) (1995). *Id.* Under this administrative regime, a Class III device for which the FDA does not yet require the usual premarket approval may be marketed if the manufacturer shows that the device is "substantially equivalent" to a device marketed before the effective date of the MDA. *Id.* The pacemakers issue in this case are also Class III medical devices, 21 C.F.R. § 870.3610 (1995), brought to market under the authority of the "substantially equivalent" process.

3 In fairness to Griffin, we note that argument was heard on Griffin's appeal before *Duvall* was decided.

However, we held in *Duvall* that the premarket notification procedure under the MDA, codified at 21 C.F.R. § 807.87 (1995) and known as 510(k) Notification, constitutes a requirement applicable to devices under the MDA because the notification procedure requires a manufacturer to submit to the FDA, among other things, certain descriptive particulars, such as proposed labels and advertisements. *Id.* at 400 ("510(k) Notification is a requirement applicable to the device under the MDA"). Thus, successful state-law claims would indeed impose a requirement in addition to a requirement already imposed on pacemakers under the MDA. Accordingly, Griffin's breach of implied warranty, strict liability, and negligence claims are preempted by § 360k.

[2] With respect to Griffin's express warranty claim, we must return the case to the district court to determine whether the claim is based on promises voluntarily made by Medtronic--and therefore, not preempted by § 360k--or whether it is based on FDA-mandated labeling, packaging, and advertising of Medtronic's pacemakers--and therefore preempted by § 360k.

III.

[3] Griffin's complaint contains one count of intentional misrepresentation. This claim alleges that Medtronic did not disclose the fact that the pacemakers were defective and unsafe for human use. Although we were not presented with an intentional misrepresentation claim in *Duvall*, we believe the rationale of *Duvall* mandates that we affirm the decision of the district court granting summary judgment for Medtronic on that claim.

[4] We reach this conclusion because the record in this case reveals no statements or other communications made to Griffin or to her physician that are any different from those made to the FDA. Thus, the premise of Griffin's intentional misrepresentation claim is that Medtronic had a duty to disclose information to Griffin and to her physician different from that which Medtronic provided to the FDA.[4] If successful,

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4 Of course, Griffin's claim might also be premised on the notion that Medtronic did not adequately comply with FDA disclosure requirements. However, the FDA alone is empowered to enforce its regulations. A private right of action seeking enforcement of FDA regulations has not been

this claim would result in the imposition of a requirement above and beyond those imposed by the MDA. Under *Duvall*, such state-law claims are preempted. Accordingly, we conclude that Griffin's intentional misrepresentation claim is preempted.

IV.

Under the authority of *Duvall*, we affirm the decision of the district court granting summary judgment for Medtronic on Griffin's negligence, breach of implied warranty, strict liability, and intentional misrepresentation claims. However, we reverse in part and remand the case with respect to Griffin's breach of express warranty claim for further proceedings not inconsistent with this opinion.

AFFIRMED IN PART; REVERSED AND REMANDED IN PART.

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recognized. *See, e.g., Rodriguez v. SK & F Co.*, 833 F.2d 8, 9 (1st Cir.1987), and cases cited therein.

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

FILED
June 6, 1996

No. 94-1219
CA-93-60-S

Griffin v. Medtronic , Inc.

MANDATE

The judgment of this Court dated 4/30/96 takes effect today.

BERT M. MONTAGUE
CLERK

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

FILED
May 29, 1996

No. 94-1219
CA-93-60-S

CATHERINE W. GRIFFIN
Plaintiff - Appellant

v.

MEDTRONIC, INCORPORATED
Defendant - Appellee

On Petition for Rehearing with Suggestion for Rehearing In Banc

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The appellant's petition for rehearing and suggestion for rehearing in banc were submitted to this court. As no member of this Court or the panel requested a poll on the suggestion for rehearing in banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied.

IT IS ORDERED that the petition for rehearing and suggestion for rehearing in banc are denied.

For the Court,

/s/ Bert M. Montague

CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CATHERINE W. GRIFFIN	*	
PLAINTIFF	*	Civil No. S 93-60
V.	*	
MEDTRONIC, INC.	*	
DEFENDANT.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

This is a product liability case, asserting numerous state-law based tort claims for injuries allegedly caused by defendant's implantable pulse generators and cardiac leads, commonly known together as "pacemakers." Both pacemakers allegedly failed after their sequential implantation in plaintiff, certain parts of the leads allegedly proved unremovable, and, it is also alleged, the consequences of these failed implantations have prevented plaintiff from properly employing her latest pacemaker to its fullest designed extent. The defendant now moves for summary judgment on the ground that plaintiff's claims are pre-empted by the so-called Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360K. The plaintiff opposes summary judgment. No oral hearing is needed. Local Rule 105.6, D.Md.

This summary judgment motion presents only an issue of law, there being no facts material to the pre-emption question in dispute. Thus, defendant may prevail only in the event it demonstrates a clear entitlement to judgment in its favor as a matter of law. Fed. R. Civ. P. 56(c).

There is no question that the alleged injuries in this case are attributed to Class III Medical Devices, regulated under the MDA. Upon

consideration, this Court has decided to follow the decisions of the First and Fifth Circuits, both of which have very recently addressed the question squarely presented in this case, viz., whether the MDA pre-empts state-law based causes of action in product liability cases involving regulated devices. Both circuits have said that such claims are pre-empted. See Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993); King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993). It would serve no useful purpose for this Court to re-hash the thorough analyses of those Circuits here.

Plaintiff's attempts to distinguish these cases are unconvincing. Both cases took full account of the Supreme Court's latest pronouncements on federal pre-emption. Both squarely dealt with the cardinal issue in this case. Neither is inconsistent with prior case law in this Circuit or District, viz., Abbott v. The American Cyanamid Co., 844 F.2d 108 (4th Cir. 1988), and Callen v. G.D. Searle & Co., 844 F.2d 662 (D.Md. 1989), in that those cases did not involve devices, but, rather, drugs. Both of those cases were decided before the Supreme Court's decision in the seminal case of Cipollone v. Liggett Group, Inc., _____ U.S. _____, 112 S.Ct. 2608 (1992), which especially calls into question the continued reliability of the discussion in Callan concerning §360K.

Finally, plaintiff argues that, even if pre-emption were to be found by the Court, it should not extend to her fraud claim. To the extent that her claim mirrors the one discussed in King, 983 F.2d at 1139-40, this Court rejects it, for the same reasons as did the King court. To the extent that plaintiff makes the claim that defendant's fraud on the medical community, including prescribing doctors, entitles her to proceed, and ultimately to relief, she is barred by Maryland's requirement that fraudulent misrepresentations must be made to the plaintiff who is claiming injury from her reliance on those representations, not to third parties. Such was the flat holding of Parlette v. Parlette, 88 Md. App. 628, 635 (1991) (opinion by Diana Motz, J.), which appears to be the only Maryland authority on point. Even in jurisdictions following a broader rule as to the class of potential fraud plaintiffs, see, e.g., Institute for Professional Dev. v. Regis College, 536 F.Supp. 632, 634 (D. Colo. 1982), the rule is that the plaintiff must be within the targeted class, i.e., those "intended to be influenced." Here, there is no allegation that defendant's fraud was targeted at consumers, as

was the case in Cipollone, but, rather at the FDA and the medical community. In any case, patients were not themselves targeted, as they obviously do not choose a particular prescription medical device such as a pacemaker, based on manufacturers' representatives or otherwise. Thus, under Maryland law as recited in Parlette, there is simply no fraud claim that survives pre-emption.

For the stated reason, an order will be entered granting summary judgment to the defendant.

Dated: January 11, 1994

/s/
Frederic N. Smalkin
U.S. District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CATHERINE W. GRIFFIN	*	
	*	
Plaintiff	*	Civil No. S 93-60
	*	
V.	*	
	*	
MEDTRONIC, INC.	*	
	*	
Defendant	*	
	*	

* * * * * * * * * * * * *

JUDGMENT ORDER

For the reasons stated by the Court in a Memorandum Opinion entered herein this date, it is, by the Court, this 11th day of January, 1994, ORDERED and ADJUDGED:

1. That the defendant's motion for summary judgment BE, and it hereby IS, GRANTED;

2. That judgment BE, and it hereby IS, ENTERED for the defendant, against the plaintiff, with costs; and

3. That the Clerk mail copies hereof and of the foregoing Memorandum Opinion to counsel.

/s/
Frederic N. Smalkin
U.S. District Judge

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Article VI of the U.S. Constitution provides in pertinent part:

> This Constitution, and the Laws of the United States...shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 360k provides:

(a) General rule

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if -
>
> > (1) the requirement is more stringent than a requirement under this chapter which would be

applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement -

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360h(d) provides:

Effect on other liability. Compliance with an order under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. § 808.1(d) provides in pertinent part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices

(e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.